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Docket Number: 037003-0280732

PATENT APPLICATION

Client Reference: 2000-30-0261VUS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of

NABIL HANNA

Group Art Unit: 1642

Application No.: 09/986,174

Examiner: Misook Yu

Filed: November 7, 2001

Confirmation No.: 4956

For: BISPECIFIC FUSION PROTEIN AND METHOD OF USE FOR ENHANCING  
EFFECTOR CELL KILLING OF TARGET CELLS

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is submitted herewith. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is being filed before the mailing date of the first official action on the merits in the present application. No certification or fee is required.

Respectfully submitted,



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**INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT**

Date: June 14, 2004 Page 1 of 3

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037003-0280732Client Ref.  
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Applicant: NABIL HANNA

Appln. No.: 09/986,174

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Examiner: Misook Yu Group Art Unit: 1642

## U.S. PATENT DOCUMENTS

Examiner's Initials*		Document Number	Date MM/YYYY	Name (Family Name of First Inventor)
	AR	4,780,530	10/1988	Teraoka
	BR	5,314,995	05/1994	Fell
	CR	5,558,864	09/1996	Bendig
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	NR	5,891,432	04/1999	Hoo
	OR	5,976,531	11/1999	Mezes

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	RR	0 706 799 B1	11/2001	EP	Hölzer		
	SR	WO 92/08495	05/1992	PCT	Gillies		
	TR	WO 98/16254	04/1998	PCT	Goldenberg		

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	UR	Behr et al., "Low- versus high-dose radioimmunotherapy with humanized anti-CD22 or chimeric anti-CD20 antibodies in a broad spectrum of B cell-associated malignancies," <i>Clin Cancer Res</i> , 1999, 5(10 Suppl):3304s-3314s.
	VR	<i>Biogen Idec v. Corixa Corp.</i> , Case No. 01-1637-IEG [Doc. Nos. 635, 662, 486] (S.D. Cal. Jan. 22, 2004).
	WR	Bonardi et al., "Delivery of saporin to human B-cell lymphoma using bispecific antibody: targeting via CD22 but not CD19, CD37, or immunoglobulin results in efficient killing," <i>Cancer Res</i> , 1993, 53(13):3015-3021.
	XR	Caron et al., "Interleukin-2 enhancement of cytotoxicity by humanized monoclonal antibody M195 (anti-CD33) in myelogenous leukemia," <i>Clin Cancer Res</i> , 1995, 1(1):63-70.
	YR	Chikkala et al., "Interactive effects of alpha-interferon A/D and interleukin 2 on murine lymphokine-activated killer activity: analysis at the effector and precursor level," <i>Cancer Res</i> , 1990, 50:1176-1182.
	ZR	Divgi et al., "Clinical comparison of radiolocalization of two monoclonal antibodies (mAbs) against the TAG-72 antigen," <i>Nucl Med Biol</i> , 1994, 21(1):9-15.
	AAR	Ellis et al., "Engineered anti-CD38 monoclonal antibodies for immunotherapy of multiple myeloma," <i>J Immunol</i> , 1995, 155(2):925-937.
	BBR	Flannery et al., "Immunomodulation: NK cells activated by interferon-conjugated monoclonal antibody against human osteosarcoma," <i>Eur J Cancer Clin Oncol</i> , 1984, 20(6):791-798.



CCR	Flavell et al., "Comparison of the performance of anti-CD7 and anti-CD38 bispecific antibodies and immunotoxins for the delivery of saporin to a human T-cell acute lymphoblastic leukemia cell line." <i>Hematol Oncol.</i> , 1995, 13(4):185-200.
DDR	Fornier et al., "Update on the management of advanced breast cancer," <i>Oncology (Huntingt)</i> , 1999, 13(5):647-58; discussion 660, 663-664.
EER	Ghetie et al., "Antitumor activity of Fab' and IgG-anti-CD22 immunotoxins in disseminated human B lymphoma grown in mice with severe combined immunodeficiency disease: effect on tumor cells in extranodal sites," <i>Cancer Res</i> , 1991, 51(21):5876-5880.
FFR	Goldmacher et al., "Anti-CD38-blocked ricin: an immunotoxin for the treatment of multiple myeloma." <i>Blood</i> , 1994, 84(9):3017-3025.
GGR	Goto et al., "A novel membrane antigen selectively expressed on terminally differentiated human B cells," <i>Blood</i> , 1994, 84(6):1922-1930.
HHR	Goulet et al., "Conjugation of blocked ricin to an anti-CD19 monoclonal antibody increases antibody-induced cell calcium mobilization and CD19 internalization," <i>Blood</i> , 1997, 90(6):2364-75.
IIR	Haisma et al., "Construction and characterization of a fusion protein of single-chain anti-CD20 antibody and human beta-glucuronidase for antibody-directed enzyme prodrug therapy," <i>Blood</i> , 1998, 92(1):184-190.
JJR	Hassan et al., "Interleukins and colony stimulating factors in human myeloid leukemia cell lines," <i>Leuk Lymphoma</i> , 1995, 20(1-2):1-15.
KKR	Hellstrand et al., "Histamine and cytokine therapy," <i>Acta Oncol</i> , 1998, 37:347-353.
LLR	<i>Idec Pharmaceuticals and Corixa Corp.</i> , Case No. 01-1637-IEG [Doc. Nos. 486, 584] (S.D. Cal. Oct. 14, 2003).
MMR	Johnson et al., "Anti-tumor activity of CC49-doxorubicin immunoconjugates," <i>Anticancer Res</i> , 1995, 15(4):1387-1393.
NNR	Kossman et al., "A phase I trial of humanized monoclonal antibody HuM195 (anti-CD33) with low-dose interleukin 2 in acute myelogenous leukemia," <i>Clin Cancer Res</i> , 1999, 5(10):2748-2755.
OOR	LeBerthon et al., "Enhanced tumor uptake of macromolecules induced by a novel vasoactive interleukin 2 immunoconjugate," <i>Cancer Res</i> , 1991, 51(10):2694-2698.
PPR	Li et al., "Pharmacokinetics and biodistribution of radioimmunoconjugates of anti-CD19 antibody and single-chain Fv for treatment of human B-cell malignancy," <i>Cancer Immunol Immunother</i> , 1998, 47(3):121-130.
QQR	Li et al., "The epitope specificity and tissue reactivity of four murine monoclonal anti-CD22 antibodies," <i>Cell Immunol</i> , 1989, 118(1):85-99.
RRR	Liu et al., "Follow-up of relapsed B-cell lymphoma patients treated with iodine-131-labeled anti-CD20 antibody and autologous stem-cell rescue," <i>J Clin Oncol</i> , 1998, 16(10):3270-3278.
SSR	Lode et al., "Natural killer cell-mediated eradication of neuroblastoma metastases to bone marrow by targeted interleukin-2 therapy," <i>Blood</i> , 1998, 91(5):1706-1715.
TTR	Macey et al., "Effect of recombinant alpha-interferon on pharmacokinetics, biodistribution, toxicity, and efficacy of 131I-labeled monoclonal antibody CC49 in breast cancer: a phase II trial," <i>Clin Cancer Res</i> , 1997, 3(9):1547-1555.
UUR	Maier et al., "Requirements for the internalization of a murine monoclonal antibody directed against the HER-2/neu gene product c-erbB-2," <i>Cancer Res</i> , 1991, 51(19):5361-5369.
VVR	Mason et al., "Value of monoclonal anti-CD22 (p135) antibodies for the detection of normal and neoplastic B lymphoid cells," <i>Blood</i> , 1987, 69(3):836-40.
WWR	Meseri-Delwail et al., "Effects of alpha-interferon on MHC unrestricted cytotoxicity in chronic myelogenous leukemia," <i>Biotechnol Ther</i> , 1994, 5(1-2):47-57.
XXR	Morrison et al., "Chimeric human antibody molecules: mouse antigen-binding domains with human constant region domains," <i>Proc Natl Acad Sci USA</i> , 1984, 81(21):6851-6855.
YYR	Myers et al., "Large scale manufacturing of B43(anti-CD19)-genistein for clinical trials in leukemia and lymphoma," <i>Leuk Lymphoma</i> , 1998, 29(3-4):329-338.
ZZR	Ngai et al., "In vitro and in vivo evaluation of streptavidin immunoconjugates of the second generation TAG-72 monoclonal antibody CC49," <i>Nucl Med Biol</i> , 1995, 22(1):77-86.
AAAR	Oldham, "Immunoconjugate: Drugs and Toxins," <i>Principles of Cancer Biotherapy</i> , 1987, Database CANCERLIT on STN, No. 88648019 (Abstract).
BBBR	Ohtomo et al., "Molecular cloning and characterization of a surface antigen preferentially overexpressed on multiple myeloma cells," <i>Biochem Biophys Res Commun</i> , 1999, 258(3):583-591.



CCCR	Okayama et al., "High-efficiency cloning of full-length cDNA; construction and screening of cDNA expression libraries for mammalian cells," <i>Methods Enzymol</i> , 1987, 154:3-28.
DDDR	Ono et al., "The humanized anti-HM1.24 antibody effectively kills multiple myeloma cells by human effector cell-mediated cytotoxicity," <i>Mol Immunol</i> , 1999, 36(6):387-395.
EEER	Ozzello et al., "The use of natural interferon alpha conjugated to a monoclonal antibody anti mammary epithelial mucin (Mc5) for the treatment of human breast cancer xenografts," <i>Breast Cancer Research and Treatment</i> , 1993, 25(3), Database EMBASE on STN No. 93198745.
FFFR	Pagliaro et al., "Humanized M195 monoclonal antibody conjugated to recombinant gelonin: an anti-CD33 immunotoxin with antileukemic activity," <i>Clin Cancer Res</i> , 1998, 4(8):1971-1976.
GGGR	Pavlinkova et al., "Radioimmunotherapy of human colon cancer xenografts using a dimeric single-chain Fv antibody construct," <i>Clin Cancer Res</i> , 1999, 5(9):2613-2619.
HHHR	Peterson et al., "Effect of multiple, repeated doses of radioimmunotherapy on target antigen expression (breast MUC-1 mucin) in breast carcinomas," <i>Cancer Res</i> , 1997, 57(6):1103-1108.
IIIR	Pitha et al., "Abnormal regulation of IFN-alpha, -beta, and -gamma expression in MAIDS, a murine retrovirus-induced immunodeficiency syndrome," <i>J Immunol</i> , 1988, 141(10):3611-3616.
JJJR	Qi et al., "Characterization of anti-tumor immunity derived from the inoculation of myeloma cells secreting the fusion protein RM4/IFN-t," <i>Hum Antibod Hybridomas</i> , 1996, 7(1):21-26.
KKKR	Rosenblum et al., "Recombinant immunotoxins directed against the c-erb-2/HER2/neu oncogene product: in vitro cytotoxicity, pharmacokinetics, and in vivo efficacy studies in xenograft models," <i>Clin Cancer Res</i> , 1999, 5(4):865-874.
LLLR	Saiki et al., "Primer-directed enzymatic amplification of DNA with a thermostable DNA polymerase," <i>Science</i> , 1988, 239(4839):487-491.
MMMR	Sausville et al., "Continuous infusion of the anti-CD22 immunotoxin IgG-RFB4-SMPT-dgA in patients with B-cell lymphoma: a phase I study," <i>Blood</i> , 1995, 85(12):3457-3465.
NNNR	Shan et al., "Characterization of scFv-Ig constructs generated from the anti-CD20 mAb 1F5 using linker peptides of varying lengths," <i>J Immunol</i> , 1999, 162(11):6589-6595.
OOOR	Sievers et al., "Selective ablation of acute myeloid leukemia using antibody-targeted chemotherapy: a phase I study of an anti-CD33 calicheamicin immunoconjugate," <i>Blood</i> , 1999, 93(11):3678-3684.
PPPR	Skrepnik et al., "Effects of anti-erbB-2 (HER-2/neu) recombinant oncotoxin AR209 on human non-small cell lung carcinoma grown orthotopically in athymic nude mice," <i>Clin Cancer Res</i> , 1996, 2(11):1851-1857.
QQQR	Sosman et al., "In vivo activation of lymphokine-activated killer activity with interleukin-2: prospects for combination therapies," <i>Semin Oncol</i> , 1990, 17(1 Suppl 1):22-30; discussion 38-41.
RRRR	Thakur et al., "Improved antibody targeting with Interferon-alpha-2b conjugate," <i>J Immunother</i> , 1997, 20(3):194-201.
SSSR	Treon et al., "Treatment of plasma cell dyscrasias by antibody-mediated immunotherapy," <i>Semin Oncol</i> , 1999, 26(5 Suppl 14):97-106.
TTTR	Van Hof et al., "Biodistribution of (111)indium-labeled engineered human antibody CTMO1 in ovarian cancer patients: influence of protein dose," <i>Cancer Res</i> , 1996, 56(22):5179-85.
UUUR	Vogel, "Current approaches of immunotargeting," <i>Immunoconjugates. Antibody Conjugates in Radioimaging and Therapy of Cancer</i> , 1987, Database CANCERLIT on STN No. 88648500 (Abstract).
VVVR	Vogel, "Antibody conjugates without inherent toxicity: the targeting of cobra venom factor and other biological response modifiers," <i>Immunoconjugates. Antibody Conjugates in Radioimaging and Therapy of Cancer</i> , 1987, Database CANCERLIT on STN No. 88648508 (Abstract).
WWWR	Vuist et al., "Enhancement of the antibody-dependent cellular cytotoxicity of human peripheral blood lymphocytes with interleukin-2 and interferon alpha," <i>Cancer Immunol Immunother</i> , 1993, 36(3):163-170.
XXXR	Webb et al., "Enhancement of monocyte-mediated tumoricidal activity by multiple interferon-alpha species," <i>Cell Immunol</i> , 1989, 124(1):158-167.
YYYR	Wiseman et al., "Radioimmunotherapy of relapsed non-Hodgkin's lymphoma with zevalin, a 90Y-labeled anti-CD20 monoclonal antibody," <i>Clin Cancer Res</i> , 1999, 5(10 Suppl):3281s-3286s.
ZZZR	Yron et al., "A human monoclonal IgA autoantibody--185/12--behaves like an autoimmune antiphospholipid antibody," <i>Clin Exp Immunol</i> , 1994, 97(2):187-192.
AAAAR	Xiang et al., "Targeting gamma interferon to tumor cells by a genetically engineered fusion protein secreted from myeloma cells," <i>Hum Antibodies Hybridomas</i> , 1996, 7(1):2-10.

Examiner	Date Considered:
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\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.